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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/183,972	10/29/98	HAGEMAN G	UIA-027.01

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EXAMINER	
TURNER, S	

ART UNIT	PAPER NUMBER
1647	20

DATE MAILED: 05/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/183,972	Hageman
Examiner	**Art Unit**
Sharon L. Turner, Ph.D.	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 2-26-01

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 2, 4-13, 23-27, and 31-45 is/are pending in the applica

4a) Of the above, claim(s) 1, 4-13, 23-27, and 31-45 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 2 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1, 2, 4-13, 23-27, and 31-45 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 19

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Response to Amendment

1. The amendment filed 2-26-01 has been entered into the record and has been fully considered.

2. Claims 3, 14-22 and 28-30 are canceled. Claims 1-2, 4-13, 23-27, and 31-45 are pending.

Election/Restriction

3. Newly submitted claims 1, and 33-45 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicants originally election invention was drawn to nucleic acids of SEQ ID Nos:1, 3 and 5 and sequences hybridizing thereto. Applicants amended claims are now drawn to following patentably distinct inventions: I. Nucleic acids encoding 72 contiguous amino acids of SEQ ID NO:6, II. Nucleic acids encoding 180 contiguous amino acids of SEQ ID NO:4, III. Nucleic acids encoding 10 contiguous amino acids of SEQ ID NO:2, IV. Nucleic acids encoding 10 contiguous amino acids of residues 42-215 of SEQ ID NO:4, V. Nucleic acids encoding 136 contiguous amino acids of residues of 221-565 of SEQ ID NO: 4, VI. Nucleic acids encoding 20 contiguous amino acids of residues 591-630 of SEQ ID NO:4, VII. Nucleic acids encoding 10 contiguous amino acids of residues 688-731 of SEQ ID NO:4, VIII. Nucleic acids encoding 5 contiguous amino acids of residues 735-743 of SEQ ID NO:4 and IX. Nucleic acids encoding residues 42-215, 221-565, 591-630, 688-731 (and 735-743) of SEQ ID NO:4. A complete search of the prior art for the nucleic acids of Groups I-IX will not reveal whether any prior art exists as to the other Groups. A search is directed to references which would render the invention obvious, as well as to

references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. Further, the claimed nucleic acids are patentably distinct because the nucleic acids represent unique structures which are not shared and are capable of distinct functions and uses.

Although the classifications for these various nucleic acids overlap, for instance 536/23.1, each represents a patentably distinct product with distinct physical and functional characteristics, alternatively classified in for example 536/23.5, 536/24.31, and 24.33. Further the search for more than one product would be burdensome, because each is claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, requires a search of the corresponding regions, reverse translations and oligomers contained therein for each representative SEQ ID NO. Thus, each individual sequence may require multiple sequence searches not required for any other sequence, to reveal prior art. Accordingly, restriction is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1 and 33-45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 4-13, 23-27, and 31-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

5. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

Rejections Maintained

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 2 stands rejected under 35 U.S.C. 101 as set forth in Paper No. 17, mailed 10-25-00 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

Applicants argue that apparently the rejection is only directed to claims 14-17 as claims 1-3 do not recite normal or abnormal IPMC genes. Applicants further argue that in accordance with the Utility Examination guidelines of January 5, 2001, Fed. Reg., 66(4):1092-99, I., Response to comment 8, that the polynucleotides undoubtedly have utility. Such is based upon the disclosure of the specification at pps. 104-105, 110 and 122, and the statement that the claimed polynucleotides are useful to the extent that they could facilitate production of proteins

encoded by the polynucleotides, that antibodies can be generated from the proteins and that such reagents can be used to further study diseases that are associated with IPM.

Applicants arguments filed 2-26-01 have been fully considered but are not persuasive. It is noted that the Federal Register response indicates that an *isolated* DNA may meet the utility requirements if it can be used to produce a *useful* protein or if it hybridizes near and serves as a marker for a disease gene. In the instant case the nucleic acid is not isolated and there is no reflection of an invention by the hand of man, but merely a recitation of a naturally occurring compound. Further, the peptide encoded by the claimed SEQ ID NO's is merely identified as originating from the interphotoreceptor matrix of the neural retina. The peptide is not specified to provide a useful product, i.e, there is no disclosed enzymatic activity, or functional property which provides immediate benefit to the public. Applicants merely argue that the IPM peptide is important to the maintenance of normal functions of the neural retina but there is no direction as to how the peptide can be used to provide for normal function, particularly in a diseased state. Similarly the specification fails to disclose any disease or abnormality associated with or treatable by the use of the claimed nucleic acids or peptide encoded thereby. Further the nucleic acids themselves fail to mark or predict any disease. Applicants arguments that the nucleic acids and peptide encoded therefrom may be used to further study diseases associated with IPM is also not persuasive as such constitutes a utility solely for research and study purposes. These acts do not in and of themselves provide an invention and the public is not accorded any immediate benefit as no useful knowledge is provided. A patent awarded for such purposes would merely

be a license for the artisan to perform further experimentation to discover the 'real world use' of the claimed nucleic acids. Thus, as previously set forth the claimed invention lacks utility.

Claim 2 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Status of Claims

8. No claims are allowed.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
May 10, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud